K003801

FEB 2 8 2001

510(k) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a 510(k) Summary of Safety and Effectiveness for the Sulzer Orthopedics® Anatomical Press-Fit Humeral Component.

Manufacturer:	Sulzer Orthopedics Ltd. Grabenstrasse 25 CH-6341 Baar, Switzerland
US Agent/Submitter:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9900
Date:	December 8, 2000
Contact Person:	Mitchell A. Dhority Manager, Regulatory & Clinical Affairs
Classification Name:	21 CFR 888.3690 - Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Common/Usual Name:	Humeral Stem Component
Trade/Proprietary Name:	Anatomical Press-Fit Humeral Stem

PRODUCT DESCRIPTION

The purpose of this submission is to seek clearance for the Anatomical Press-Fit Humeral Stem. This product builds on the general design philosophy of the previously cleared cemented Anatomical Humeral Stem (K990137), thus broadening the product line with a press-fit option.

The stem is made of a hot forged titanium alloy (Ti-6Al-7Nb, Protasul-100, ISO 5832/11). The stem is offered in 4 sizes (7, 9, 12, 14) based on stem diameter.

The stem is straight and features a "trumpet shaped" proximal geometry to match the metaphysis of the humeral shaft. Fixation of the stem is press-fit (cementless). Rotational control and firm fixation are achieved via flutes which run longitudinally down the stem. The outer surface of the stem may also be lightly roughened to provide further stability. Holes in the proximal aspect of the stem body allow for attachment of tuberosities via sutures/wires.

Similar to the previously cleared cemented Anatomical Stem (K990137), the stem features a slit-ball head, fixed at an angle of 135°, which allows for unique attachment of one of the previously cleared humeral heads used with the system. The previously cleared impact screw and expansion cone are inserted through a shaft in the lateral aspect of the stem and into the slit-ball head at the time of surgery. This forces the slit-ball feature to spread open allowing fixation of. The use of the slit ball has the advantage of allowing fixation of the head in a variety of angles. The previously cleared traumatology cone identical to the expansion cone, except with positioning pegs for head placement, is also available.

SPECIFIC DIAGNOSTIC INDICATIONS

The Anatomical Press-Fit Humeral Stem is intended for press-fit use in treatment of the following:

1. Advanced wear of the joint due to degenerative, post-traumatic or rheumatic diseases.
2. Fractures or avascular necrosis.
3. Conditions consequent to earlier operations.

SUBSTANTIAL EQUIVALENCE

The Anatomical Press-Fit Humeral Stem is similar to the cemented Anatomical Humeral Stem cleared via K990137. The main difference is that it is a cementless, press-fit design made of titanium alloy instead of a cemented design manufactured from stainless steel alloy.

The Anatomical Press-Fit Humeral Stem is also similar to the Sulzer Orthopedics Select Shoulder, the Kirschner/Biomet Atlas Shoulder, the Kirschner/Biomet Mod II-C Shoulder, the Biomet Bio-Modular Total Shoulder, and the Depuy Global Total Shoulder System.

These devices are similar in terms of design features and materials. Additionally, the subject and predicate devices share similar indications for use. The subject device, like the predicate devices, are used generically in the treatment of noninflammatory and inflammatory joint disease as well as prosthetic revision.

Testing did not raise any new issues of safety or effectiveness and indicated that this device should provide performance equivalent to commercially marketed products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2001

Mr. Mitchell A. Dhority, RAC
Manager, Regulatory & Clinical Affairs
Sulzer Orthopedics, Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K003801
Trade Name: Anatomical Press-Fit Humeral Stem
Regulatory Class: II
Product Codes: KWS and HSD
Dated: December 7, 2000
Received: December 8, 2000

Dear Mr. Dhority:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Mr. Mitchell A. Dhority, RAC

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003801

Device Name: Anatomical Press-Fit Humeral Stem

Indications for Use:

The Anatomical Press-Fit Humeral Stem is intended for press-fit use in treatment of the following:

1. Advanced wear of the joint due to degenerative, post-traumatic or rheumatic diseases.
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** _____

(Optional Format 1-2-96)

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003801